EXHIBIT L

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January 27, 2020

VIA PRIORITY MAIL

DHHS – OMHA
Centralized Docketing
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

BENEFICIARY APPEAL

RE: Request for ALJ Hearing
Beneficiary: Anniken Prosser
W2973 Farmstead Dr.
Appleton, WI 54915
HICN: 4R87U71QM75
Device: Tumor Treatment Field Therapy (E0766)
Supplier: Novocure, Inc.
Dates of Service: 5/16/2019; 6/16/2019; 7/16/2019; 8/16/2019
Medicare Appeal No: 1-9079666355
Date of QIC Decision: January 21, 2020
Our Ref: 19-719

Dear Claims Coordinator:

As an authorized representative of the above-captioned Medicare beneficiary, I hereby appeal to an Administrative Law Judge the above-captioned decision rendered by the Qualified Independent Contractor ("QIC") Maximus Federal Services, Inc. for the claims submitted for tumor treatment field therapy ("TTFT") for a glioblastoma. The QIC denied the claims arguing that the device is not reasonable and necessary per LCD L34823. For the reasons stated below, the LCD should not be applied against the beneficiary.

For reference, the DME contractors have issued a revised coverage policy for TTFT. They concede that the evidence to support coverage was in place by 2017 at the latest, given their reliance on the Stupp 2017 publication of the EF-14 trial results, which was a study that incorporated newly diagnosed and recurrent patients. When the LCD revisions were published, an LCD challenge was pending before the Civil Remedies Division. Under 42 C.F.R. §426.420(b), "a contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the ALJ issues a decision regarding the LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under §426.460(b)." Under §426.460(b), an ALJ finds

that an LCD is not valid under the reasonableness standard. Accordingly, the claim must be adjudicated without application of the invalid LCD. See §426.460(b)(1)(i) and (iv). If the LCD is revised, as in the case with LCD L34823, the revised LCD is applied to services that are performed after the effective date of the revised LCD. See §426.460(b)(1)(ii).

Moreover, in a separate administrative proceeding challenging LCD L34823, the Administrative Law Judge with jurisdiction over the case issued an interim ruling, based upon his independent assessment of the LCD record, that the LCD record is insufficient to support the validity of the LCD (CRD C-19-396 Order). A copy of the Order was attached to the reconsideration request on CD. The LCD record is devoid of any developments after 2014 in the treatment of patients diagnosed with a glioblastoma.

The beneficiary was diagnosed with a glioblastoma and her clinician prescribed TTFT. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2015, the FDA approved, through its more rigorous review process, a device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. During the clinical trial for newly diagnosed glioblastomas, such as that of Ms. Prosser, the TTFT results were so compelling that at the interim analysis, the Data Safety Monitoring Board recommended that those not receiving TTFT be able to cross over to receive the treatment. The FDA agreed.

The published, peer-reviewed literature shows the improved clinical survival and the progression-free survival of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network ("NCCN") guidelines and is considered the standard of care for newly diagnosed glioblastoma. Hundreds of treating physicians, in all 50 states, have prescribed TTFT. TTFT is covered by all the large national payers. Medicare has paid for numerous claims for medically indistinguishable beneficiaries.

With respect to the LCD, the previously submitted documents show that the LCD has not kept pace with the current peer-reviewed literature, regulatory status, consensus of experts, scientific evidence or adoption by the relevant medical community. Indeed, the LCD record shows that the DMACs have failed to update the LCD to reflect consideration of developments that have occurred over the past five years and only considered recurrent GBM. On March 6, 2019, the Carrier Advisory Committee recommended Medicare coverage of TTFT. The experts found that the peer-reviewed literature showed the treatment was safe and effective.

Finally, Medicare coverage for Ms. Prosser's TTFT device has already been decided; two prior final favorable Level III decisions were submitted with the reconsideration request. Accordingly, the Secretary is estopped from denying coverage of TTFT on the same basis for the same device for the same beneficiary.

(continued on next page)

If you have any questions, please do not hesitate to contact me at (412) 561-6250.

Yours very truly,

Debra Parrish on behalf of
Ms. Anniken Prosser

*AOR submitted below with the reconsideration request

cc:

Anniken Prosser W2973 Farmstead Dr. Appleton, WI 54915	Novocure, Inc., c/o Justin Kelly 195 Commerce Way Portsmouth, NH 03801 (603-501-4299)

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February 20, 2020

VIA PRIORITY MAIL

Attn: Judge Sardinas
HHS OMHA Irvine Field Office
19 Technology Dr., Suite 200
Irvine, CA 92618-2364

RE: Prehearing Brief
ALJ Appeal No. 3-9079666355
Appellant/Beneficiary: A. Prosser
Service: E0766
Dates of Services: 5/16/19 – 8/16/19
Hearing Date: To Be Determined
Our Ref. No.: 19-719

Dear Judge Sardinas:

Please find attached a prehearing brief to assist in your analysis of the above-captioned case, in anticipation of its scheduling.

The QIC has not been forwarding the CD we submit at reconsideration with the administrative record. If the CD is not present in the file as forwarded to your office, please let us know and we will resubmit a copy of the CD. Alternatively, we would be happy to review an Exhibit List, once generated, to determine if the contents of the CD are present.

If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,

Debra M. Parrish
Attorney for A. Prosser

Enclosures:
Prehearing Brief

cc: Ms. Prosser

A. Background

Ms. Anniken Prosser is a 36-year-old mother (of a six-year-old son), wife, and Medicare beneficiary. She enjoys drawing, writing and singing lyrics for two bands, and spending time with her family and friends. Unfortunately, in February 2016 she was newly diagnosed with a glioblastoma (GBM) after experiencing intractable migraines. She had surgery and chemoradiation. She completed chemoradiation in May 2016. Consistent with the standard of care, her clinician then prescribed the Optune system to treat her glioblastoma. She began using the Optune system in June 2016 with adjuvant temozolomide. She was prescribed the device as a newly diagnosed patient. Importantly, the July 17, 2019 treatment note reflects a KPS score of 80. The supplier submitted claims for the Optune system to the relevant Durable Medical Equipment Contractor (DMAC) which denied the claims.

The QIC denied the claims, arguing that the device is not reasonable and necessary per LCD L34823. As described more fully below, the denial is inconsistent with Medicare coverage criteria and the record.

The issue of Medicare coverage was already adjudicated for Ms. Prosser. Claims for the same device for the same beneficiary were the subject of two favorable ALJ decisions which are final, which found that the device was reasonable and necessary for Ms. Prosser for multiple months preceding the dates of service at issue in this case (attached to the reconsideration request). In view of the foregoing, the Secretary is estopped from denying claims on the same basis. Please see discussion below.

The DME contractors issued a revised LCD providing for coverage of TTFT for newly diagnosed glioblastoma during the pendency of an LCD challenge. They rely upon evidence that was published by 2017 at the latest, which predates the dates of service at issue. See e.g., revised LCD citing EF-14 study (Stupp), attached on CD to the reconsideration request. **By virtue of this revision, the LCD that was applied to Ms. Prosser's claim is deemed invalid under the reasonableness standard. 42 CFR § 426.420; 42 CFR § 426.460.**[1]

Moreover, in the separate administrative proceeding challenging LCD L34823, the Administrative Law Judge with jurisdiction over the case issued an interim ruling, based upon his independent assessment of the LCD record, that the LCD record is insufficient to support the

[1] Pursuant to 42 C.F.R. §426.420, the revision of an LCD after a challenge has been filed has the same effect as a judicial ruling that the LCD was invalid. Under 42 C.F.R. §426.420(b), "a contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the ALJ issues a decision regarding the LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under §426.460(b)." Under §426.460(b), an ALJ finds that an LCD is not valid under the reasonableness standard. Accordingly, the claim must be adjudicated without application of the invalid LCD. See §426.460(b)(1)(i) and (iv).

validity of the LCD (see Order on CD attached to the reconsideration request). The LCD record is devoid of any developments after 2014 in the treatment of patients diagnosed with a glioblastoma. Such a policy should not be applied against the beneficiary in this case and used to deny coverage for a treatment that is recognized as safe and effective by the published literature, consensus of experts, and widespread adoption of the treatment.

1. Glioblastoma Multiforme (GBM)

Glioblastoma is a very rare (~10,000 US cases annually) primary brain cancer. The National Institutes of Health (NIH) designate glioblastoma multiforme as a rare disease, with few treatment options. See e.g., https://rarediseases.info.nih.gov/diseases/2491/glioblastoma. GBM tumors are typically highly aggressive. Without treatment, life expectancy on diagnosis is 3 months. Even with aggressive chemotherapy treatment, survival at initial presentation is approximately 10 months, and upon recurrence, approximately 6 months.[2] Because it is extremely rare for glioblastoma to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy.

2. Optune (formerly NovoTTF-100A System)

Optune, previously known as the NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or "Tumor Treating Fields" to the brain. The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patient's scalp and deliver the Tumor Treating Fields Therapy ("TTFT") to the patient's glioblastoma. Basically, the fields interfere with/slow the replication of the cancer cells or stop their growth all together. The fields may also destroy some of the cancer cells.

Optune is FDA-approved for recurrent and newly diagnosed glioblastoma multiforme (GBM) brain tumors. Devices that are FDA approved through the PMA process as class III devices are those that "support or sustain human life or are of substantial importance in preventing impairment of human health." On January 1, 2014, CMS classified the Optune device as DME requiring frequent and substantial servicing, which is billed under HCPCS code E0766 as a monthly rental through the duration of medical necessity. Optune has been shown to extend the lives of patients suffering from glioblastoma tumors.

B. Literature/Professional Societies

Optune is the subject of numerous peer-reviewed published studies that demonstrate the safety and efficacy of the Optune system and TTFT generally. The QIC's assertion that the literature lacks sufficient scope and breath and peer-review is belied by the evidence. More than 130 peer-reviewed publications address TTFT clinical data. More than 470 publications support

[2] Rulseh et al. "Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields." World Journal of Surgical Oncology at 1 (2012).

TTFT's mechanism of action – electrical field disruption of mitotic spindle formation as a means of cell death. The clinical studies are reported in some of the most prestigious journals in our country including JAMA (the Journal of the American Medical Association). See submitted studies. The studies concluded the following:

- The final analysis of the randomized phase 3 trial (695 patients) found that the addition of Optune to standard chemotherapy treatment "resulted in statistically significant improvement in progression-free survival and overall survival" over patients that were treated with chemotherapy alone. Stupp et al. at 2315 (JAMA 2017). See also, interim analysis of 315 patients from this study (adding Optune to maintenance chemotherapy "significantly prolonged progression-free and overall survival"). Stupp et al. at 2542 (JAMA 2015).

- At the same time, more than 23 randomized trials of new treatment modalities or products for glioblastoma over a ten-year period all "failed to demonstrate improved survival." JAMA 2017 at 2314-2315.

- Remarkably, adding Optune to traditional chemotherapy treatment "resulted in statistically significant longer deterioration-free survival in global health status, physical and emotional functioning, pain, and weakness of legs." Taphoorn et al. at E7 (JAMA Oncology 2018).

- As far back as 2012, researchers reported that in a study of 237 patients that received either Optune treatment or chemotherapy that the Optune treatment was at least as effective as chemotherapy alone in terms of median survival, without the toxicity risks. Stupp et al. at 8-9 (European J of Cancer 2012).

Indeed, the Data Safety Monitoring Board for the clinical trial for newly diagnosed glioblastoma (and patients that suffered recurrences during the trial) found the data so compelling, they recommended early termination and allowing patients who were not receiving TTFT to be able to cross over and receive the treatment, deeming it unethical to withhold it. The FDA agreed. Please see the submitted bibliography regarding TTFT which shows numerous peer-reviewed articles published on TTFT and its clinical application.

Optune is included in the National Comprehensive Cancer Network (NCCN) guidelines for recurrent glioblastoma and for newly diagnosed GBM in combination with temozolomide. See submitted guidelines. The NCCN guidelines are translated in multiple languages and used around the world. In particular, for cases of newly diagnosed glioblastoma, the NCCN guidelines (considered the gold standard for oncology management) give a level one recommendation for TTFT, i.e., a consensus exists among the experts based on the high level of evidence, that the treatment is recommended. Thus, a consensus exists that the published peer-reviewed literature demonstrates the effectiveness of the device for newly diagnosed glioblastomas.

Further, a March 6, 2019 Carrier Advisory Committee meeting concluded that the peer-reviewed evidence supports Medicare coverage.[3] Thus, the very experts the DMACs assembled indicated that the literature supports coverage. As noted above, on July 18, 2019, the DMACs issued a final LCD extending coverage of TTFT for individuals who have newly diagnosed GBM.

C. Widespread Adoption

Based on the strength of the peer-reviewed literature and the lack of medical alternatives, the Optune system has been certified at more than 800 cancer treatment centers, and has been prescribed by over 1100 physicians in 50 states, the District of Columbia, and Puerto Rico, for over 7200 patients. It is used in 59 of the 62 NCI designated cancer centers. Virtually every major payer in the United States covers the Optune system for individuals diagnosed with a glioblastoma. These payers include, among others, Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans. Approximately 250 million Americans have access to TTFT through their insurers.

TTFT is so widely accepted that it is included in medical school textbooks. See CD attached to reconsideration request.

D. The LCD

As noted above, on July 18, 2019, the DMACs issued a final LCD extending Medicare coverage of TTFT. Because the LCD was revised after an LCD challenge had been filed, it had the same effect as a judicial ruling the LCD was invalid. See 42 C.F.R. §§ 426.420; 426.460. Thus, the invalid LCD, made invalid by the operation of the applicable Medicare regulations, should not be applied to the claims.

In either event, the new LCD explicitly extends coverage for individuals who have newly diagnosed GBM when they start using Optune, such as this Medicare beneficiary. If the DMACs had timely completed the LCD reconsideration process as they were required to, this case likely would not have been brought.

E. Prior Level III Favorable Decisions

Ms. Prosser has received prior favorable Level III decisions that have not been appealed and are final. Please see the decisions attached to the reconsideration request. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues. As noted by a unanimous Supreme Court:

[3] Although the video of this meeting is required to be posted, the DMACs have not posted the meeting,

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

See Astoria Federal Savings and Loan Assoc. v. Solimino, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). The application of issue preclusion would not work as basic unfairness against the Secretary and there are no special circumstances that would make it unfair to apply the doctrine.

F. Reimbursement Amount

If Medicare coverage is found, payment for DME is made under a regulation, 42 C.F.R. §414.210(a), which states that:

> *. . . Medicare pays for [DME] . . .on the basis of 80 percent of the lesser of:*
>
> *(1) the actual charge for the item; [or]*
> *(2) the fee schedule amount for the item, as determined in accordance with §§414.220 through 414.232.*

Because no fee schedule existed on the dates of service, payment is 80% of the amount billed. See also Medicare Appeal Council Decision for ALJ 1-178898474.

G. Conclusion

This is the technology that clinicians treating central nervous system tumors have embraced. No basis exists to deny Medicare coverage of a device that is shown in the peer-reviewed literature to be a safe and effective treatment for glioblastoma, a life-threatening condition. The Optune system was approved as safe and effective by the FDA. The peer-reviewed literature further supports its efficacy and the improved clinical outcome of patients who use the device. It is incorporated in the NCCN guidelines (considered the gold standard for

cancer care), and it enjoys widespread adoption by clinicians and all the major payors in the United States based on the foregoing. The DMAC medical directors had indicated the prior version of the LCD did not apply to newly diagnosed glioblastomas and issued a revision that extends Medicare coverage. TTFT has already been found to be reasonable and medically necessary for this beneficiary. The Medicare beneficiary has no reasonable medical alternatives. The claims should be approved.